PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 47956/288203	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/US04/31886	International filing date *(day/month/year)* 29 September 2004 (29.09.2004)	Priority date *(day/month/year)* 30 September 2003 (30.09.2003)
International Patent Classification (IPC) or national classification and IPC IPC(7): A61F 2/06 and US Cl.: 623/1.12		
Applicant ALVEOLUS INC.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 3 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *(sent to the applicant and to the International Bureau)* a total of 2 sheets, as follows:
      ☐ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) ____ , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items:
   - ☒ Box No. I Basis of the report
   - ☐ Box No. II Priority
   - ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - ☐ Box No. IV Lack of unity of invention
   - ☒ Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - ☐ Box No. VI Certain documents cited
   - ☐ Box No. VII Certain defects in the international application
   - ☐ Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
04 August 2005 (04.08.2005)	03 October 2005 (03.10.2005)
Name and mailing address of the IPEA/ US Mail Stop PCT, Attn: IPEA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Authorized officer Brian Pellegrino Telephone No. 703-308-0858

Form PCT/IPEA/409 (cover sheet)(April 2005)

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International Application No.
PCT/US04/31886

Box No. I Basis of the report

1. With regard to the **language**, this report is based on:
   - ☒ the international application in the language in which it was filed.
   - ☐ a translation of the international application into English, which is the language of a translation furnished for the purposes of:
     - ☐ international search (under Rules 12.3 and 23.1(b))
     - ☐ publication of the international application (under Rule 12.4(a))
     - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
   - ☐ the international application as originally filed/furnished
   - ☒ the description:
     pages 1-12 as originally filed/furnished
     pages* NONE received by this Authority on _____
     pages* NONE received by this Authority on _____
   - ☒ the claims:
     pages NONE as originally filed/furnished
     pages* NONE as amended (together with any statement) under Article 19
     pages* 14 and 15 received by this Authority on 04 August 2005 (04.08.2005)
     pages* NONE received by this Authority on _____
   - ☒ the drawings:
     pages 1-5 as originally filed/furnished
     pages* NONE received by this Authority on _____
     pages* NONE received by this Authority on _____
   - ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages _____
   - ☐ the claims, Nos. _____
   - ☐ the drawings, sheets/figs _____
   - ☐ the sequence listing (*specify*): _____
   - ☐ any table(s) related to the sequence listing (*specify*): _____

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages _____
   - ☐ the claims, Nos. _____
   - ☐ the drawings, sheets/figs _____
   - ☐ the sequence listing (*specify*): _____
   - ☐ any table(s) related to the sequence listing (*specify*): _____

** If item 4 applies, some or all of those sheets may be marked "superseded."*

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US04/31886

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 8,10,11	YES
	Claims 1-7,9	NO
Inventive Step (IS)	Claims NONE	YES
	Claims 1-11	NO
Industrial Applicability (IA)	Claims 1-11	YES
	Claims NONE	NO

2. Citations and Explanations (Rule 70.7)

Claims 1-7,9 lack novelty under PCT Article 33(2) as being anticipated by Giantureo et al. '706. Giantureo discloses (Fig. 6) a stent with interconnected annular segments and have the support frame partly surrounded by a thread **40** that is interwoven in the eyes. Fig. 4 shows the stent is tubular and that deflection elements **20** are arranged on the circumference of the frame and on the end-side. Fig. 5 also shows the deflection has deflection elements **20'** arranged on the inner side of the stent facing the middle and the adjacent annular segment **10"** has a deflection element **20"**. Fig. 10B shows thread ends **56** coupled by connector **70** since they extend together in the tube. With respect to claim 9, it can be construed that additional guide elements are provided in the frame, see Fig. 3.

Claim 8 lacks an inventive step under PCT Article 33(3) as being obvious over Giantureo et al. Giantureo is explained above. Giantureo fails to disclose the connector tube is of a material that is x-ray visible. It is well known in the art to use radiopaque markers in delivery tubes. It would have been obvious to incorporate a marker in the connector tube of Giantureo to permit the surgeon to better see the end of the device as they remove the stent.

Claims 10,11 lack an inventive step under PCT Article 33(3) as being obvious over the prior art as applied in the preceding paragraph regarding Giantureo and further in view of Cox. Giantureo fail to disclose the annular segments are formed by struts in an endless corrugated manner, coupled with connector struts or a longitudinal section or spine running along the longitudinal axis. Cox shows (Figs. 2,9)a spine or longitudinal section along the axis. Cox teaches that the continuous spine prevents the stent from shortening longitudinally and helps prevent the stent from storing energy as the sheath is retracted It can also be seen the strut section has a U-shape and is transverse with the spine since
they extend across the spine. It would have been obvious to one of ordinary skill in the art to use a spine to join the annular segments as taught by Cox in the stent of Giantureo such that it prevents foreshortening of the stent upon implantation.

Applicant's remarks have been considered but are unpersuasive with respect to the Giantureo reference.
---------- NEW CITATIONS ----------

CLAIMS:

1. A stent with a tubular support frame (2) consisting of axially successively following, interconnected annular segments (3, 4, 5), wherein said support frame (2) is surrounded on its outside by a thread (11), characterized in that the thread ends (12, 13) are guided via a deflection (14) from the outside into the support frame (2), where they are coupled by a connector (17).

2. The stent according to Claim 1, characterized in that the deflection (14) is realized at least one deflection element (15, 16; 19, 20; 22, 23; 26, 27) provided on an annular segment (3, 4).

3. The stent according to Claim 1 or 2, characterized in that the deflection (14) is formed by two deflection elements (15, 16; 19, 20; 22, 23; 26, 27) arranged on the circumference of the support frame (2) with an interval (A) from one another.

4. The stent according to Claims 1 or 2, characterized in that the deflection (14) is provided on an end-side annular segment (3), viewed in the direction of the longitudinal axis (L) of the stent.

5. The stent according to Claims 1 or 2, characterized in that the deflection (14) is arranged on an inner side, facing the middle of the stent, of the annular segment (3).

6. The stent according to Claims 1 or 2, characterized in that the deflection (14) is formed by two deflection elements (19, 20; 22, 23) of which a first deflection element (19; 22) is arranged on an inner side, facing the middle of the stent, of an annular segment (3) and that the second deflection element (20; 23) is arranged on an outer side of the annular segment (3).

AMENDED SHEET

7. The stent according to Claim 3, characterized in that the deflection (14) is formed by two deflection elements (26, 27) of which a first deflection element (26) is provided on the end-side annular segment (3), viewed in the direction of the longitudinal axis (L) of the stent, and a second deflection element (27) is provided on the adjacent annular segment (4).

8. The stent according to one of the Claims 1 or 2, characterized in that the connector (17) consists of a material visible in x-rays.

9. The stent according to one of Claims 1 or 2, characterized in that guide elements (28) are provided in the support frame (2).

10. The stent according to one of Claims 1 or 2, characterized in that the annular segments (3, 4, 5) are formed by struts (6, 7) that follow one another in an endless, corrugated manner and that adjacent annular segments (3, 4, 9) are coupled by connector struts (8, 8').

11. The stent according to Claim 10, characterized in that each connector strut (8, 8') comprises a longitudinal section (9) running substantially parallel to the longitudinal axis (L) of the stent and comprises a strut section (10) aligned transversely to the latter and configured in a U shape or V shape.